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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	**No. 2:15-MD-02641-DGC** **PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TINLIN CASE-SPECIFIC OPINIONS OF ROBERT M. MCMEEKING, PH.D.**

Plaintiff Debra Tinlin, ("Plaintiff") opposes Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc.'s ("Bard"), Motion to Exclude The Tinlin Case-Specific Opinions of Robert M. McMeeking, Ph.D. ("Motion" or "Mot.").

I. INTRODUCTION

Although it appears to paint with a broad brush, in the Conclusion to its Motion, Bard asks this Court to preclude Dr. McMeeking from testifying regarding three things: (1) "alternative designs," (2) "whether any specific alternative design would have reduced the risk of harm experienced by Ms. Tinlin," and (3) "opinions regarding Bard's alleged 'choices' in designing the Recovery Filter." Mot. at 17. While conceding that Dr. McMeeking has previously offered opinions "criticizing the testing and design of Bard's retrievable IVC filters, including the Recovery filter," Bard claims that Dr. McMeeking's case-specific opinions "go[] significantly farther," to reach the question of whether the design defects caused Ms. Tinlin's injuries. Mot. at 1.

But, Dr. McMeeking's opinions in *Tinlin* go no farther than those to which he previously testified in three separate trials before this Court, and Bard points to no specific opinion in Dr. McMeeking's case-specific report that even plausibly does so. In his prior MDL reports and testimony, Dr. McMeeking identified multiple design defects in the Recovery filter, Bard's failures to properly test the design of the filter, as well as alternative design features that Bard failed to incorporate in its filters, including the Recovery. He has also previously opined and testified that, as a result of those failures, the Recovery suffers specific device failures when implanted in humans, including tilt, migration, perforation, and fracture. And, he opined and testified that, for each of the plaintiffs in the bellwether trials, the failures suffered by their particular filters are of the kind that result from the design defects in the filter. And, this Court has previously determined that Dr. McMeeking's opinions on these topics are appropriate, helpful to juries, and admissible.

In Ms. Tinlin's case, Dr. McMeeking merely applies those design-related opinions to the filter implanted in Ms. Tinlin, noting that her filter "experienced all of the failure modes consistent with the defects inherent in the Recovery filter." *Tinlin* Rep., at 2. There is nothing new here, and this Court should deny Bard's Motion in its entirety. Moreover, even if this were entirely new opinion testimony, Bard's Motion simply raises issues for impeachment that can be adequately addressed through cross-examination at trial. A ruling at this stage is premature. Finally, Bard has again failed to identify with specificity the opinions that it complains are inadmissible. Accordingly, the Court should defer ruling on these objections until trial. *See* ECF No. 10051, at 4 (denying Bard's motion to exclude Dr. McMeeking's opinions and noting lack of clarity on "what opinions in the reports seek to exclude").

II. DR. MCMEEKING'S QUALIFICATIONS

Dr. Robert McMeeking holds a Bachelor of Science degree in mechanical engineering (1st Class Honours) from the University of Glasgow and both a Master of Science as a Doctorate in Engineering from Brown University. He is currently the Tony Evans Professor of Structural Materials and Professor of Mechanical Engineering at the Engineering Department of the University of California, at Santa Barbara, California. Dr. McMeeking is a member of the U.S. National Academy of Engineering and a Fellow of the U.K. Royal Academy of Engineering. He

also served a full 10-year term as Editor of the American Society of Mechanical Engineers Journal of Applied Mechanics, finishing in 2012. The American Society of Mechanical Engineers is the leading U.S. professional society concerned with stress/strain analysis, and the Journal of Applied Mechanics is its leading professional publication addressing stress/strain analysis. Dr. McMeeking has testified on several occasions to the Food and Drug Administration on issues pertaining to the in vivo loading, stress/strain analysis, fatigue, fracture and endurance of medical implants.

III. BACKGROUND AND LEGAL STANDARD

The federal standard for the admissibility of expert evidence is explained in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). There, the Court rejected *Frye*'s general acceptance test and concluded that Federal Rule of Evidence 702 "assign[s] to the trial court the task of ensuring that a scientific expert is qualified" and that his or her "testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. The trial court is not the fact finder however. When credible, qualified experts disagree, a litigant is entitled to have the jury, not the trial court, decide which expert to believe. *Dorn v. Burlington N. Santa Fe R.R. Co.*, 397 F.3d 1183, 1196 (9th Cir. 2005).

The reliability standard "entails a preliminary assessment of whether the reasoning or methodology is scientifically valid." *Daubert*, 509 U.S. at 592-93. Reliability depends "solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (*Daubert* requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

Dr. McMeeking's opinions in this case meet the standards of *Daubert*.

IV. ARGUMENT

A. Dr. McMeeking's Opinions Are Reliable and Will Assist the Jury.

In forming his opinions, Dr. McMeeking first conducted an assessment of the Recovery filter. See prior MDL Reports dated March 3, 2017, April 7, 2017, April 21, 2017, and May 12, 2017, attached collectively as Exhibit A. This assessment was performed in the manner that is typically applied by mechanical engineers during the design and verification stages of the

manufacturing of devices such as biomedical implants. For Dr. McMeeking, this process included the review of thousands of pages of documents produced by Bard, numerous peer-reviewed scientific and medical articles, deposition testimony from relevant witnesses, and FDA materials. *See* Dr. McMeeking's Reliance Materials attached as Exhibit B; *see also* Deposition of Robert M. McMeeking, PhD, NAE, FRSE, January 30, 2019 ("Dep."), attached as Exhibit C, at 22:12-23, 24:15-19, 101:17-102:2, 104:20-105:6, 111:1-7. In addition to review of these materials, Dr. McMeeking performed his own calculations utilizing well-recognized and accepted engineering principles and methodologies. *See* Dep. at 47:15-23, 65:24-66:1, 99:1-16, 100:2-101:15, 109:15-110:16, 111:1-7, 111:15-22. Dr. McMeeking also reviewed and relied on the expert reports of Drs. Hurst and Muehrcke. Dep. at 103:6-10. The procedures are broadly accepted in the field of engineering for the evaluation of the safety and effectiveness of medical devices. According to the FDA, computational modeling and simulation studies are tools that can be used to evaluate the safety and effectiveness of medical devices. *See* "Reporting of Computational Modelling Studies in Medical Device Submission/Draft Guide for Industry and Food and Drug Administration Staff, FDA Document # 1807 (January 17, 2014), attached as Exhibit D.

1. Dr. McMeeking's Opinions on Alternative Design Features were Previously Disclosed, Have Been Offered in the MDL Trials, and are Reliable and Admissible.

As a starting point, Dr. McMeeking has previously disclosed the very opinions as to alternative design features that are set forth in his *Tinlin* case-specific report. His March 3, 2017, MDL report identified the smoother rounded chamfer feature at page 12. His May 11, 2017, rebuttal report in the MDL identified the two-tier design of the SNF as an improved design feature at page 3. And, at his main MDL deposition on July 6, 2017, Dr. McMeeking identified caudal anchors and penetration limiters as additional alternative design features to improve the filters:

> Q Are there any other changes that you think Bard later made to its filters that it could have made earlier --
>
> A Yes.
>
> Q -- to -- to impact resistance to complications?
>
> A Yes.

> Q All right. And what are those?
>
> A They could have developed caudal anchors sooner than they ultimately did. They could have developed penetration limiters sooner than they ultimately did. And they could have redesigned the filter configuration to try and find a better -- a better combination of -- of -- of phenomena that would improve the behavior of the filter in terms of the risks involved.
>
> Q All right. So let's talk about caudal anchors and limiters. On what do you base your opinion that Bard could have added caudal anchors and limiters earlier than it did?
>
> A Well, the -- the reason is that they eventually did put caudal anchors on the filters, and so my point is simply that they could have started to consider that possibility sooner than they -- they did, once they realized that caudal migration was contributing to tilt and tilt was contributing to other failures that the filter was experiencing.

McMeeking July 6, 2017, MDL Deposition Transcript at 32-33, attached hereto as Exhibit E.

Further, Dr. McMeeking has testified to these very design features in the bellwether trials. The opinions on these design features have already been determined admissible by this Court. *See* Trial Transcript of *Hyde v. C.R. Bard, Inc., et al*, at 619:8-623:19, attached hereto as Exhibit F; *Jones v. C. R. Bard, Inc.*, et al., at 406:3-407:25, 408:3-410:1, attached hereto as Exhibit G; *Booker v. C.R. Bard, Inc.*, et al. at 569:25-598:19, attached hereto as Exhibit H. *See* Jones trial transcript at 408-410 (addressing smoother chamfer, caudal anchors, and penetration limiters),

Dr. McMeeking used relevant engineering principles in forming his opinions regarding the safer alternative design features. He confirmed this when he agreed that he applied the principles he uses in his capacity as a mechanical engineer in reaching his decisions. Dep. at 98:19-25. Dr. McMeeking specifically testified in this case that he conducted calculations in forming his opinion that a rounded cap, the chamfer, would be an effective feature of an alternative design. Dep. 21:1-22:3. He presented calculations in his MDL report to show the levels of strain and stress. Dep. at 47:25-23. As a result, Dr. McMeeking arrived at his conclusions regarding the chamfer using the principles of mechanical engineering. Dep. at 100:11-101:13.

As to the penetration limiters and caudal anchors, Dr. McMeeking testified regarding his knowledge of literature discussing these design feature's efficacy and comparing filters that have those features versus the filters that do not have those features. Dep. at 62:22-63:4. Significantly,

as Bard well knows, these design features exist on Bard's later generation devices, the Meridian and Denali; and Dr. McMeeking has reviewed those devices and issues reports regarding them in this MDL. When Dr. McMeeking was questioned whether there is any filter manufacturer who incorporated caudal anchors or penetration limiters in a retrievable filter, Dr. McMeeking testified that he was aware of the Cook Gunther Tulip and that the Tulip came out on the market in 2002 or 2003. Dep. at 71:12-22.

Bard takes issue with Dr. McMeeking's opinions because he allegedly did not "test" any of the alternative design feature (Mot. at 14-15) to argue that Dr. McMeeking did no work to verify the accuracy of his opinions. But, that argument is misleading. "Daubert does not require an expert to test every single element leading to an expert's conclusions." *Cooper v. Toshiba Home Tech. Corp.*, 76 F. Supp. 2d 1269, 1278-69 (M.D. Ala. 1999) (other citations omitted). Indeed, Dr. McMeeking testified that an expert in his profession would not normally "test" the devices or design features but would rather perform calculations:

> Q. And in coming to those conclusions and opinions, did you follow a methodology that is utilized by reasonable engineers in your field to resolve these issues?
>
> A. I did, yes.
>
> Q. And did you apply the same methods and processes that are used by mechanical engineers in arriving at those opinions.
>
> A. Yes, I did.
>
> Q. In order to come to your opinions as to the design and testing of the Bard IVC filters, <u>was it necessary for you to carry out bench testing or animal testing?</u>
>
> A. <u>No. It was not.</u>
>
> Q. And do mechanical engineers in your role typically carry out bench testing or animal testing?
>
> A. Well, many of them carry out bench testing. But animal testing would be an unusual pursuit for a mechanical engineer of my background and professional activities.

Dep. at 109:22 -110:16 (emphasis added).[1]

[1] Similarly, Bard's reliance on *Nease v. Ford Motor Co.*, 848 F.3d 219 (2017), is also misleading. In *Nease*, the expert conducted only a visual inspection and inappropriately relied on a document which applied to another vehicle model,

Moreover, as noted above, Dr. McMeeking performed his own calculations and finite element analysis as to certain features and functions. And, he also applied principles of sound mechanical engineering in arriving at his conclusions. Thus, Bard's Motion should be denied.

2. Dr. McMeeking's Opinions on Case-Specific Issues are Reliable and Admissible.

Bard also moves to exclude Dr. McMeeking's opinions relating the defects of the Recovery filter to Plaintiff specifically. But Dr. McMeeking's opinions on this issue are also reliable, admissible, and no different than those he has offered before. It is not clear precisely what opinion Bard believes to be objectionable.[2] The only opinion that Bard cites from his *Tinlin*-specific report on this point is at page 3 of its motion, where Bard block-quotes Dr. McMeeking's opinions concerning reasonable alternative designs and alternative features that he "previously identified." That opinion, also cited on the first page of Bard's motion, goes no farther than Dr. McMeeking has before; it remains focused on design failures and notes that the plaintiff's filter failed in ways that are attributable to those failures.

Dr. McMeeking first testified on these issues in the *Booker v. C.R. Bard, Inc. et al*. trial just over a year ago. In *Booker*, Dr. McMeeking laid the foundation for his design defect opinions and then further concluded "that the failure of Ms. Booker's filter was caused by [the] deficiencies in design and testing." Ex. H, at 546:10-12. Bard did not object to this testimony. This testimony continued with the following exchange:

> Q. So when you say you have also a third area of opinions on the impact that the design and the lack of testing had on Ms. Booker, that's your opinion?
>
> A. That's right.
>
> Q. And what is your opinion in that regard?

not the vehicle at issue in the case. *Id.* at 224-25. Moreover, the expert in that case failed to offer any data or any studies or records relating to his safer alternative design opinions. *Id.* at 334. Here, Dr. McMeeking is relying on volumes of internal Bard documents, scientific literature, his own hand mathematical calculations, computer simulations (Finite Element Analysis), and the medical records in this case to form his opinions.

[2] Rather than identify with specificity the opinions at issue, as the Court previously held it should (ECF No. 10051, at 4), Bard invites the Court to review Dr. McMeeking's entire deposition transcript. Mot. at 11 n.3.

> A. Oh, my opinion is that because of the inadequacies of the design and of the testing of the filter, that those inadequacies led to the failure of Ms. Booker's failure after it was implanted in her.

Id. at 546:13-21. Bard did not object to the introduction of this testimony.

Dr. McMeeking testified in the *Booker* trial that in reaching his conclusions, he looked at the conditions the filter would go through, the failure modes, and did calculations of the stresses and strains to assess whether the failure modes would be problematic after implant. *Id*. at 554:10-20. Dr. McMeeking also reviewed tests, including bench tests. *Id*. at 554:21-23. Again, Bard did not object to this testimony.

In the next trial, *Jones v. C. R. Bard, Inc.*, Dr. McMeeking again testified that some of the opinions he had in the case included "the impact that the defective design of the filter had on the filter that is in Mrs. Jones." Ex. G, at 348:18-23. In this trial, again, Defendants make no objection. The same exchange that occurred in *Booker*, occurred here again:

> Q. Do you have any opinions with respect to the effect of those designs and testing failures on the filter that Mrs. Jones had?
>
> A. Yes. It is my opinion that those defects in the design caused the problems that Mrs. Jones suffered from her filter.

Id. at 350:7-11. Again, Bard made no objection.

In the most recent trial, *Hyde v. C.R. Bard, Inc.*, a side-bar discussion included the following exchange with, most notably, Bard's counsel acknowledging these opinions as "fair game."

> MR. O'CONNOR: He said in his case-specific report that . . . [t]he failures of Ms. Hyde's filter resulted from poor design, inadequate testing prior to marketing the filter, and implantation of the filter – and implantation --- prior to implantation of the filter in Mrs. Hyde, and improper internal assessment of the filter via analysis, including finite analysis and other methods of analysis utilized by Bard.
>
> So I believe that sums his opinions in this case and where's he going to go.
>
> THE COURT: All right. Ms. Helm, do you have a problem with what Mr. O'Connor just read as an opinion to be stated?
>
> MS. HELM: Your Honor, those opinions, to use a term I've heard you say before, are all fair game.

Ex. F, at 524:7-25.

Dr. McMeeking's case-specific opinions in this case are the same type of opinions that were deemed admissible in the three prior trials.

Further, Bard's suggestion that Dr. McMeeking violates this Court's order regarding the identification of the Simon Nitinol Filter as a safer alternative design is illusory. This Court's Order precludes Dr. McMeeking from testifying that the Simon Nitinol Filter is a safer alternative in a particular plaintiff because Dr. McMeeking is not a medical doctor. It does not preclude Dr. McMeeking from testifying that one of the many features, namely the two-tiered design, of the Simon Nitinol Filter is safer than the Recovery filter generally. This very testimony has been admitted in three prior trials. *Supra.*, at A.1.

B. The issues in Bard's Motion are cross-examination issues, not basis for preclusion under *Daubert*.

The purpose of a *Daubert* inquiry is to scrutinize proposed expert witness testimony to determine if it has "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field" so as to be deemed reliable enough to present to a jury. *Kumho Tire*, 526 U.S. 137 at 152. If the proposed expert testimony meets the *Daubert* threshold of relevance and reliability, the accuracy of the actual evidence is to be tested before the jury with the familiar tools of "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof." *Daubert*, 509 U.S. 579, 596, 113 S. Ct. 2786, (1993).

Bard's motion seeks to exclude the "opinions" that caudal anchors, penetration limiters, a two-tiered design, and a better chamfer at the cap would have prevented Ms. Tinlin's filter failure. Bard's motion also seeks to exclude that certain competitors incorporated these designs. Bard seeks exclusion based on Dr. McMeeking not considering certain information it considers pertinent. This is an area ripe for cross-examination, not a *Daubert* ruling.

Further in its motion, Bard claims that Dr. McMeeking did not consider Plaintiff's medical history. This is simply untrue. Dr. McMeeking read and relied on Plaintiff's medical records and the expert reports of Drs. Muehrcke and Hurst who opine on specific causation. Dr. McMeeking considered this information. Dep. at 101:17-102:2. Bard can address the reasons why Dr.

McMeeking did not consider certain information pertinent versus the information that he did at that point in the trial but it would be improper for the Court to exclude this testimony altogether. Defendant's litany of issues with Dr. McMeeking's discussion of alternative filters are also topics for cross-examination for the same reasons, not the basis for a *Daubert* motion and thus Bard's motion is due to be denied at this stage.

C. The Court Should Not Exclude Dr. McMeeking's Opinions On Bard's Design Choices.

Bard's last argument seeks to the exclude Dr. McMeeking's Opinions Regarding Bard's choices on the design of the Recovery. The Court should not grant Bard's motion on this issue. At best, this argument is too tenuous to exclude at this point. Dr. McMeeking's opinions and testimony are reliable and will assist the jury by educating them on the information that Bard had within its internal files at the time it was designing the Recovery filter and the design feature it ultimately used. This testimony goes to the very heart of Plaintiff's safer alternative design claims. If Bard knew of the problems with the design of the Recovery filter yet disregarded that knowledge for whatever reason or failed to make any changes that Bard knew would minimize the risk of harm, Dr. McMeeking should be authorized to explain that to the jury. This is not corporate motive or intent testimony and therefore should not be excluded. *See* Dep. at 82:4-22.

V. CONCLUSION

Based on the foregoing reasons, Plaintiff Debra Tinlin respectfully requests that the Court deny Bard's Motion in its entirety, or, alternatively, refrain from ruling until hearing Dr. McMeeking's qualifications and testimony at trial.

RESPECTFULLY SUBMITTED this 4th day of March, 2019.

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CERTIFICATE OF SERVICE

I hereby certify that on this 4th day of March 2019, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/Jessica Gallentine